

**SUMMARY OF THE FIRST ANNUAL
NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE**

**February 14 - 16, 1995
Arlington, Virginia**

The first annual National Environmental Laboratory Accreditation Conference (NELAC) was opened by Executive Secretary Ms. Jeanne Mourrain of the Environmental Protection Agency. The three-day conference was presided over by NELAC Chairman Dr. Robert Stephens, Chief of the State of California Hazardous Materials Laboratory. The meeting was attended by more than 370 representatives of Federal and state governmental organizations, interested trade associations, laboratory accreditation organizations, environmental testing laboratories, industry, and the general public. Attendees included representatives from 50 states and territories, all of EPA's Headquarters programs and Regional Offices, and 15 other Federal government organization.

The purpose of the meeting was to review and discuss the draft NELAC constitution and proposed NELAC standards which were published in the *Federal Register* on December 2, 1994 (59 FR 62178 - 62215). Dr. Robert Huggett, EPA's Assistant Administrator for Research and Development, provided the welcoming address. He emphasized that NELAC's purpose is to reinvent the Nation's environmental laboratory oversight program. On behalf of EPA, Dr. Huggett encouraged the conference participants to work toward a program that incorporates the broad range of data needs in the environmental and public health communities, both nationally and internationally. He also emphasized that engendering full, voluntary reciprocity among state environmental laboratory accreditation programs will be key to the success of NELAC. Dr. Huggett noted that the proposed structure for NELAC, based on voluntary participation by the states, sets it apart from other environmental programs because it provides an opportunity for meaningful investment by the Federal government, the states and the private sector, unlike traditional environmental programs that have been handed down by EPA to the states in accordance with traditional statutory procedures.

The NELAC Director, Ms. Ramona Trovato, Director of EPA's Office of Radiation and Indoor Air, reviewed the Conference objectives and operating principles. Ms. Trovato emphasized that the draft constitution and standards published on December 2, 1994 represent an initial working draft for the Conference. She advised the Conference to view their job as the beginning of the process. Noting the complexity and overwhelming size of the job to be done - that of establishing consensus standards for laboratory accreditation and reaching agreement on a structure for a national program, Ms. Trovato asked the Conference participants to keep their expectations practical and to listen with an open mind to all perspectives represented at the Conference.

Objectives for the First Annual Conference, as presented by Ms. Trovato, included:

1. Reaching agreement on a fundamental philosophy for NELAC based on the need to for uniform national laboratory evaluation standards and voluntary adoption of the standards by the states;
2. Reaching agreement on an initial working structure for NELAC so that it can continue to make progress towards its ultimate goal of a uniform national program over the coming year;

3. Conducting open, participatory discussions on the policy issues and scientific aspects of the draft NELAC constitution and proposed standards in order to begin the process of finding workable approaches to national environmental laboratory accreditation that maximize benefits to all stakeholders.

Ms. Trovato provided a brief overview of the five-year history of EPA's national environmental laboratory accreditation initiative. She also noted that the first annual conference represents an important decision point for EPA because the results of the meeting will allow EPA's Environmental Monitoring Management Council to decide whether to continue to work toward a national program, based on the level of interest and commitment expressed by the states.

The opening session of the Conference was concluded with a review of the proposed organization and structure for NELAC, which includes: a Board of Directors consisting of NELAC elective officers and six members at large; a Conference Director and Executive Secretary, to be appointed by EPA; six administrative committees; seven standing committees; a House of Representatives consisting of one representative from each state, appointed by the Governor, two representatives appointed by each of the seven Assistant and Associate Administrators of EPA, and one representative each from other participating Federal government agencies and organizations; a House of Delegates consisting of all other Federal and state government officials attending the Conference; and a body of Contributors consisting of all state and federal participants. The proposed constitution and bylaws designate all members of the Board of Directors, the House of Representatives and the House of Delegates as voting members. Contributors are designated as non-voting members.

Administrative committees of the Conference are as follows:

Conference Management and Funding Committee, to be responsible for preparing the annual NELAC budget for approval by the Board of Directors and for overseeing the interim and annual meetings.

Nominating Committee, to be responsible for presenting a slate of nominees for all elective offices at the annual meeting.

Membership Committee, to be responsible for initiating membership invitations and publicizing the Conference.

Fiscal Auditing Committee, to be responsible for arranging for annual audits of Conference financial records.

Liaison Committee, to act as liaison for NELAC with international organizations, Federal agencies and other groups and organizations.

Contributor's Committee, to serve as the focal point for NELAC Contributors.

NELAC Standing Committees are:

Program Structure Committee, responsible for developing modifications to the scope, structure and requirements to the tiers and fields of testing which comprise the technical framework for NELAC accreditation.

Accrediting Authority Committee, responsible for providing the standards used by EPA to approve state accrediting authorities.

Quality Systems Committee, responsible for establishing and updating the key elements of QA/QC, including record keeping and staffing requirements.

Performance Evaluation Testing Committee, responsible for determining the requirements and structure of the Performance Evaluation Program.

On-Site Assessment Committee, responsible for designing the on-site assessment component of the program, including determining training and experience requirements for assessors.

Accreditation Process Committee, responsible for developing modifications for the laboratory accreditation process, including procedures for suspension, revocation and denial of accreditation and related appeals processes.

Regulatory Committee, responsible for providing the standing committees with current information on Federal regulations that affect laboratory testing.

After discussion, during which it was agreed by the Chair that the Constitution would be carefully discussed and revised as necessary, the Constitution was adopted on a pro tem basis until the second annual NELAC meeting. Adoption provided 1) an organizational and procedural framework for the Conference, 2) allowed for additional discussion on proposed amendments and establishment of a procedure for considering and adopting Constitutional amendments, and 3) provided an organizational framework for the Standing and Administrative Committees to consider their areas of concern.

Plenary discussion included comments regarding the Good Laboratory Practices (GLP) versus NELAP standards and requirements. A recommendation was made from the floor that a subcommittee, including contributors, be set up to ensure that the two programs are compatible.

The Program Structure Committee met and reported the following recommendations at the plenary session:

Recommendation 1: The Pro Tem Constitution and By-laws be amended to clarify that federal agencies be accrediting authorities, to reconfirm that all EPA laboratory evaluations will be brought under the umbrella of NELAC and to recognize that programs centrally managed by EPA and other federal agencies may continue as currently administered unless they replicate existing state program activities.

Recommendation 2: The conflicting language in the Pro Tem Constitution and By-laws regarding “elected” vs. “appointed” committee members be corrected to “appointed”.

Recommendation 3: The Program Structure Committee (Section 3,B1 of the Pro Tem By-laws) be renamed the Program Policy and Structure Committee and reassign the duties of the Board of Directors

in Article IV, Section 2B, to this committee, since this committee has been assigned responsibility for the Constitution and By-laws.

Recommendation 4: Article VII, Section 2,B., of the Pro Tem By-laws be amended to allow EPA to be represented in the House of Representatives by one member from each of the seven Assistant/Associate Administrators and one member from each EPA Region selected by their respective Assistant/Associate or Regional Administrators.

Recommendation 5: The NELAC Board of Directors submit a letter to EPA requesting a two year FACA charter for environmental laboratory accreditation to provide private sector consensus advice to the EPA Administrator.

Recommendation 6: Subject to legal review, the Standing and Administrative Committees be expanded from five to ten participants with the five additional participants being from the contributors but without vote.

Recommendation 7: Seating in all plenary sessions be open except in voting sessions where the members of the Housing of Representatives and House of Delegates must be grouped for ease of tallying votes.

Recommendation 8: The Education and Outreach Committee be added to the Pro Tem By-laws as Article VI, Section 3, Part B. This committee develops informational materials to promote understanding of the importance of consistent standards for environmental sampling and analysis which will foster data of the appropriate quality on which to base environmental decisions.

The Program Structure Committee recommendations were voted on by the NELAC on February 16, 1995. The voting results were as follows:

	<u>REPRESENTATIVES</u>		<u>DELEGATES</u>	
	<u>YEA</u>	<u>NAY</u>	<u>YEA</u>	<u>NAY</u>
RECOMMENDATION 1	60	5	65	3
RECOMMENDATION 2	64	1	81	1
RECOMMENDATION 3	59	1	74	1
RECOMMENDATION 4	63	2	68	5
RECOMMENDATION 5	59	3	76	1
RECOMMENDATION 6	57	9	74	4
RECOMMENDATION 7	65	2	84	1
RECOMMENDATION 8	64	1	74	4

The remaining two days of the Conference consisted of working meetings of each of the standing and administrative Committees. The meetings were designed to allow full and open discussion of all aspects of the proposed standards by all participants and to achieve agreement on how each committee should proceed toward its stated mission and objectives. The Conference closed with a plenary session, presided over by Dr. Stephens, in which numerous matters were put to vote, including the addition of one standing committee on Education and Outreach and several amendments to the constitution and by-laws.

A brief synopsis of each standing committee report follows.

The Standing Committee on **Accrediting Authority** is the committee established to provide standards used by EPA to approve state authorities. This committee proposed four subcommittees: 1) EPA auditing team members and qualifications; 2) components of evaluation; 3) the evaluation “approval” process; 4) ethics and conflict of interest issues. The Committee reported that NELAC and the NELAC Accreditation Authority Committee will begin developing standards that the USEPA and future state and federal accreditation authorities must meet to become NELAC Recognized Accreditation Authorities. The following documents will be used as reference: ISO Guide 58, CNAEL Report, Guidelines for EPA to Evaluate Accreditation Authority, NELAC Draft Standards for Roles and Responsibilities of the Federal Government, the States and other Parties, and other international laboratory accreditation documents. It is expected that these draft standards will be available for the next annual NELAC. Discussion included the issue of a laboratory's status when the laboratory's accrediting authority loses its accreditation, and a recommendation that other committees also review ISO 58.

The **Quality Systems Committee** is charged with developing standards for a uniform quality assurance and quality control system and keeping current on key elements of QA/QC. Section 5 of the Draft Standards was reviewed in its entirety by the Committee during its working session. The primary issue was the relationship of Section 5 to ISO 25, with an option being substitution of ISO 25 for Section 5 of the NELAC Draft Standards. Six subcommittees were proposed: 1) application of standards to air sampling; 2) application of standards to GLP; 3) biomonitoring; 4) personnel requirements and the need to specify standards; 5) standards as they relate to the nuclear industry; and 6) electronic data and records. Issues discussed ranged from including contributors as active committee members to proscriptive standards.

The **Performance Evaluation Committee (renamed Proficiency Testing)** is responsible for determining the requirements for the Performance Evaluation Program, generating the standards for the Performance Evaluation samples, providing criteria for selection of the provider of the Performance Evaluation samples, and providing and updating the protocol for the use of the Performance Evaluation Program in the accreditation of laboratories. Three subcommittees were established: 1) storage of samples; 2) kind of sample; and 3) frequency and number

of test samples. Issues discussed included the importance of proficiency testing. There was general agreement with the performance evaluation section, and that proficiency testing is essential, with cost not being the major concern.

The **On-Site Assessment Committee** is responsible for determining the training and experience requirements of the assessors, establishing the frequency of inspection, generating the procedures for on-site visits and publishing these standards in a National Environmental Laboratory Accreditation Manual. The Committee reviewed Section 3 of the Draft Standards, and made the following recommendations for action: 1) that a subcommittee be formed to evaluate training requirements of on-site assessors, and 2) that a subcommittee be formed to design checklists and forms for the on-site assessors.

The Committee on the **Accreditation Process** is responsible for generating and developing modifications of the accreditation process for environmental laboratories, including the requirements for accreditation, procedures of suspension, revocation and denial of accreditation, relative roles and responsibilities of laboratories and appeal processes. The committee considers matters concerning reciprocity of accreditation and establishes the process for the approval of state/federal accrediting authorities. The Committee reviewed Section 4, discussed the issues on which the State/EPA group focus group have reached consensus as well as presented the issues that still require further discussion, and recommended that subcommittees be formed to consider the following issues: 1) personnel qualification, 2) timing and guidelines, 3) corrective action, 4) ethical standards, 5) the application process, 6) certification of compliance, 7) period of accreditation, and 8) mandatory accreditation.

The **Regulatory Committee** (renamed **Implementation Committee**) provides the Standing Committees with current information on federal regulations that impact laboratory testing. The scope of the Committee includes all matters regarding the development and interpretation of uniform laws and regulations, the study and analysis of bills for legislative enactment, and the establishment and maintenance of published guidelines and other effective means of encouraging uniformity of interpretation and application of laboratory requirements. The Committee shall also provide model language to assist states in adopting the standards in state statutes. During the Conference, the Regulatory Committee reviewed programs in the following twelve states: Arizona, California, Delaware, Iowa, Maryland, Massachusetts, Michigan, Mississippi, New York, North Carolina, South Carolina, and Virginia. Statutory authority, the fee structure, and reciprocity were compared. A major conclusion was that no legislation should be proposed if it doesn't promote the streamlining of the accreditation process.

Legislative concerns were reviewed, including multi-media draft standards, a tiered approach to certifying laboratories, development by the states of a fee structure section, reciprocity, "out of business" and new technology clauses, statutory authority to incorporate NELAC standards into certification rules, record maintenance, enforcement authority, and reporting requirements to regulatory agencies. The focus for the Committee will be continuation of its investigation of how existing programs are implemented. The Committee requested that Contributors be allowed to participate without vote, and that the board communicate to NELAC any changes in government regulations or international quality standards impacting the NELAC standards or the field of testing.

The **Significance of Data Quality Committee** (renamed **Education and Outreach**) recommended the following language be added to Article VI, Section 3, Part B: "8. Education and Outreach Committee. This committee develops informational materials to promote understanding of the importance of consistent standards for environmental sampling and analysis which will foster data of the appropriate quality on which to base environmental decisions." The draft Fact Sheet was reviewed and revised by the Committee and the group proposed that three subcommittees be formed: 1) Fact Sheet - to follow up on the draft Fact Sheet, 2) Cost/Value Added to determine cost benefits of NELAC implementation by tasks in comparison to existing programs and

research examples of value added by the program, and 3) Newsletter - to report progress of NELAP activities and educate interested parties about the benefits of the program.

Throughout the Conference, several themes emerged as the most important issues of policy to be addressed in the coming year. These were:

1. The role of the private sector in the NELAC process.

Conference participants expressed overwhelming agreement concerning the importance of providing a meaningful and effective process for incorporating the technical contributions and policy perspectives of non-government participants, such as laboratories, industry and the general public. EPA and state representatives cautioned that extending voting privileges to NELAC Contributors would present issues of administrative procedure, as states and EPA take steps to incorporate NELAC standards into state and Federal regulations and statutes. EPA representatives emphasized a continuing commitment to pursuing establishment of a charter under the Federal Advisory Committee Act (FACA) to facilitate full participation by Contributors in NELAC standard-setting processes.

2. Including established Federal laboratory accreditation programs under the NELAC framework.

Considerable discussion was devoted to the issue of how best to incorporate established Federal laboratory accreditation programs in the NELAC framework. EPA representatives expressed a commitment to finding workable approaches to incorporating such Federal programs without delegating new responsibilities to the states and without disrupting existing program processes and organizations. The goal of including all EPA programs in NELAC is to ensure that EPA's laboratory oversight programs are achieving a uniform minimum standard of reliability.

3. Ensuring that NELAC accreditation will be accepted internationally.

Throughout discussions on technical standards for laboratory accreditation, participants emphasized the need to be consistent with similar standard-setting activities underway in the international community. Many recommendations were made to achieve consistency with international standard-setting organizations such as the International Standards Organization (ISO).

At the close of the Conference, participants expressed overwhelming support for continuing NELAC. Active members voted by overwhelming majority to adopt the proposed constitution and by-laws on an interim basis for a period of one year. Working agendas were established for each of the administrative and standing committees and steps were taken to ensure that each committee consists of fully representative membership, with the private sector represented in a non-voting capacity until such time as the issue of their participation can be resolved.

Committees will begin meeting as soon as possible to work toward achieving the agendas established at the Conference, with the goal of preparing to report on progress at the first Interim Meeting, to be held during the summer of 1995. Each committee will work toward developing proposals that can be put to a vote of the full Conference at the annual meeting in 1996.

A straw poll was requested on the question: *"Should we continue the process of developing national standards for environmental lab accreditation with the goal of establishing a national program of uniformly applied standards?"* Strong support for continuation of the effort was indicated by the "yea" vote. GLP contributors

did not, however, vote for such inclusion as shown in the following straw vote tally:

<u>STRAW POLL</u>			
		<u>YEA</u>	<u>NAY</u>
<i>CONTINUE WITH NELAC</i>			
HOUSE OF REPRESENTATIVES		61	4
DELEGATES	65	1	
GLP CONTRIBUTORS		5	41
NON-GLP CONTRIBUTORS	47	5	

The Conference elected Dr. Eldert C. Hartwig, Jr., Laboratory Services Administrator for the State of Florida Department of Health and Rehabilitative Services to be NELAC Chair-Elect. Dr. Hartwig's term as Chair of NELAC will commence at the next Conference.

The next steps include publication of the Conference summary. Each Conference participant was asked to brief their office. Ramona Trovato, NELAC Director, recalled for the Plenary Session the short and successful history of the NELAC effort which began five years ago with a visit of private sector representatives to USEPA asking if standardization would be possible. She offered special recognition to the following individuals for their leadership and accomplishments: Charles Hartwig, Jr., the Vice-chair of CNAEL and NELAC Chair-Elect, Robert Stephens, NELAC Chair, Jeanne Mourrain, NELAC Executive Secretary, and to each member of the Environmental Monitoring Management Council *Ad Hoc* Panel on Laboratory Accreditation.

Closing remarks were made by William Raub, Science Advisor to the Administrator of USEPA, during which he emphasized the importance of quality science and data, and commended the hard work and achievements of those participating in the NELAC process and conference.